



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,904	11/27/2000	Michael H. Julius	47841/00063	4246

33721 7590 07/20/2004

TORYS LLP  
79 WELLINGTON ST. WEST  
SUITE 3000  
TORONTO, ON M5K 1N2  
CANADA

EXAMINER

TELLER, ROY R

ART UNIT PAPER NUMBER

1654

DATE MAILED: 07/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/721,904	<b>Applicant(s)</b> JULIUS ET AL.	
	<b>Examiner</b> Roy Teller	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 170-176, 180, 199-202, 222-223 and 226-230 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 170-176, 180, 199-202, 222, 223 and 226-230 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)<br>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)<br>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____.<br>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)<br>6) <input type="checkbox"/> Other: _____. |
|---|--|

Art Unit: 1654

### **DETAILED ACTION**

This office action is in response to applicant's response, received 7/12/04, in which applicant cancelled claims 159, 161-163, 177-178, 181-191, 193-195, 198, 224-225, and 231-255, and amended claims 170, 180, 199, 223, and 227.

The finality of the previous final office action, dated 11/14/03, is withdrawn.

Claims 170-176, 180, 199-202, 222-223, and 226-230 are pending.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 199-202, 222-223, and 226-230 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 199-202, 222-223, and 226-230 read on non-elected embodiments such as SEQ ID NO: 5, 6, and 7, making the claim improper and indefinite. It is suggested that the claims be amended to read on the elected invention, SEQ ID NO:4.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 170-176, 180, 199-202, 222-223, and 226-230 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diamond (Proc. Natl. Acad. Sci., vol. 93, pp 5156-5160, May 1996) in view of Julius (USPN 6,093,693).

The claimed invention is drawn to a method of stimulating expression of defensin by administering a compound comprising soluble CD14 to epithelial cells of a mammal. The protein has an amino acid sequence of at least about 63%, 68%, 71%, 73%, 78% 83%, 88%, 93%, or 98% conserved in relation to SEQ ID NO:4.

Diamond teaches tracheal epithelial cells exposed to bacterial lipopolysaccharides express CD14, see abstract. Diamond discloses a widespread mechanism of host defense in the animal kingdom is the production of antibiotic peptides/ defensins, see page 5156, column 1, paragraph 2. Diamond teaches the soluble form of CD14 can mediate lipopolysaccharide-stimulated responses in epithelial cells, see page 5157, column 2, paragraph 4. Diamond discloses *in vivo* evidence for increased expression of B-defensin lingual antibiotic peptide in the squamous epithelium of the tongue, see page 5159, column 2, paragraph 2. Diamond does not teach a structure of CD14.

Julius teaches a method of activating B cells in a mammal, by administering CD14, see abstract. Julius discloses SEQ ID NO: 4 which is a 100% query match with SEQ ID NO:4 of the instant application, see STIC search. Julius teaches that CD14 can be administered to an infant, by incorporating CD14 into infant formula, see abstract. Julius discloses CD14 protein purified from bovine colostrum whey, see abstract.

Applicant's arguments were carefully considered but were not found persuasive

Applicant contends that the invention defined by the claims require stimulating or enhancing expression of at least one defensin by directly exposing epithelial cells or epidermis to soluble CD14 (or equivalent), is neither taught, nor suggested by the teachings of Diamond, alone or in combination with Julius. However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have added the teachings of Diamond to protein of Julius in order to enhance expression of antibiotic peptides/ defensins because Diamond teaches that many mammalian epithelial cells have the capacity for analogous host defense responses.

### ***Conclusion***

All claims are rejected.

Art Unit: 1654

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

RT  
1654  
7/15/04

KT



CHRISTOPHER R. TATE  
PRIMARY EXAMINER